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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,368	09/17/2003	Jens Ulrik Poulsen	6133.224-US	4554

7590 06/23/2010
Reza Green, Esq.
Novo Nordisk Pharmaceuticals, Inc.
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Princeton, NJ 08540

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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06/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,368	Applicant(s) POULSEN ET AL.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/05/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/462,128.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/05/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

The Examiner acknowledges the reply filed 05/05/2009 in which claim 1 was amended. Currently claims 1-3 and 9 are pending for examination in this application.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 05/05/2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Interference

Regarding the suggested interference with U.S. Patent No. 6,544,212 filed 05/05/2009, the Examiner will consider the suggested interference proceeding according to MPEP 2304.02(c), 2304.04(a) and 37 CFR 41.202 once the claims are in condition for allowance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 9 are rejected under 35 U.S.C 103(a) as being unpatentable over Castellano et al. (USPN5,536,249). Castellano et al. discloses a pen-type injector with a microprocessor and blood monitor.

Regarding claims 1-3 and 9, Castellano recites a system comprising and insulin delivery unit (Col. 5 lines 25-26); a blood glucose monitor (Col. 5 lines 26-28); and a master module including a processor (Col. 7 lines 15-21; col. 14 lines 31-39; col. 16 lines 23-28). Castellano does not specifically recite transmitting the dose of insulin to the insulin delivery unit; however, he does disclose an I/O port capable of receiving and transmitting (Col. 14 lines 42-49). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Castellano to not only receive data from the insulin delivery unit, but also to transmit data back to it in order to facilitate and expedite data flow. Further Castellano recites a microprocessor receiving other data (Col. 8 lines 4-7). Claim 3 is rejected as the type of data stored is non-functional descriptive material that does not further limit the system disclosed (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Response to Arguments

Applicant's arguments filed 05/05/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Castellano reference does not disclose the communication/master module being configured to predict the dose of

insulin and transmit an expected dose of insulin, and that this limitation is not obvious to one of ordinary skill in the art.

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the (I/O) port of Castellano (col 8, ln 10-60) discloses an input/output port that is configured to transmit data back and forth with specific respect to the user/patient. Castellano discloses (col 8, ln 20-30) that the port can be used to download user stored information and for updated program instructions. The Examiner asserts that this port is configured to transmit expected dose data from either patient (see Figures 24a-d) (col 14, ln 25-40) or practitioner for controlled diabetes treatment (based upon sensed trends stored in the RAM 324), which is congruent with the teachings on Castellano.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 06/21/2010

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/

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Supervisory Patent Examiner, Art Unit 3763